

REMARKS/ARGUMENTS

The Examiner has made final the following rejections of claims 9, 11, 13-17, 19 and 20:

1. Claims 9, 11, 13-17, 19 and 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by JP '511 as evidenced by Sato;
2. Claims 9,11 and 19-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hino; and
3. Claims 13-17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hino.

For the reasons set forth hereinafter, it is requested that the Examiner reconsider and withdraw these final rejections.

Claims 9 and 11

In claims 9 and 11, a hydroxyapatite complex has the structure as illustrated in Fig. 1 herein, i.e. the structure in which a hydroxyl group adhered on the surface of a non-modified hydroxyapatite sintered compact is chemically bonded directly to an alkoxysilyl group contained in a polymer-based material.

On the contrary, JP 2001-172511 (hereinafter referred to as "JP 511") discloses in the paragraph [0049] that a calcium phosphate particle and a polymer-based material are chemically bonded by carbamate bonding obtained by a reaction of (a) an amino group that is an active group introduced into a calcium phosphate particle and (b) a carboxyl group that is an active group introduced into a silicone rubber sheet (i.e. polymer-based material). Therefore, a calcium phosphate-polymer complex disclosed in JP 511 has the structure as illustrated in Fig. 2 herein.

Thus, the hydroxyapatite complex of the present invention is totally different in structure from the calcium phosphate-polymer complex disclosed in JP 511.

Fig. 1

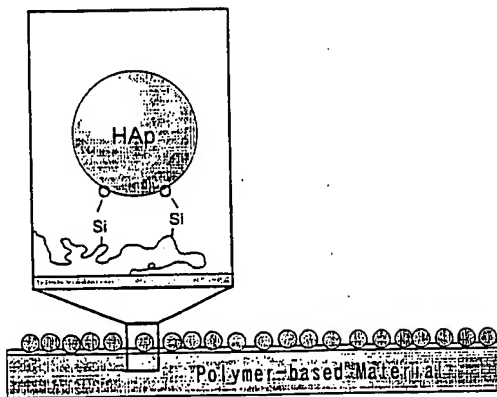
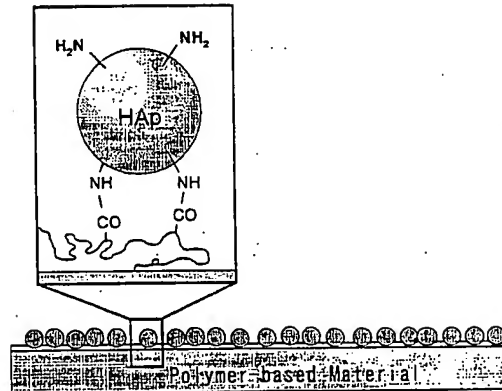


Fig. 2



In addition, JP 511 discloses in the paragraph [0043] that a hydroxyl ion contained in the calcium phosphate particle itself can be used in bonding the calcium phosphate particle to the polymer-based material.

However, JP 511 does not disclose and suggest that the polymer-based material contains an alkoxysilyl group, and the alkoxysilyl group is chemically bonded directly to a hydroxyl ion contained in the calcium phosphate particle itself. That is, JP 511 does not disclose and suggest the hydroxyapatite complex having the structure illustrated in Fig. 1 herein.

As described above, the hydroxyapatite complex recited in claims 9 and 11 has a unique structure that is not disclosed and suggested in JP 511. Therefore, both claims 9 and 11 should be allowable over JP 511.

Claims 19 and 20

In claims 19 and 20, the hydroxyapatite complex has the structure in which a hydroxyl group of a hydroxyapatite sintered compact and an alkoxysilyl group of a polymer-based material containing the alkoxysilyl group, which is expressed as $-\text{Si}(\text{OR})_3$, are chemically bonded.

That is, in the present invention, the hydroxyapatite sintered compact is not modified with a silane coupling agent such as KBE9 03 (i.e. 3 -minopropyltriethoxysilane).

Therefore, in the hydroxyapatite complex of the present invention, the hydroxyapatite sintered compact is not covered with a silane coupling agent, as illustrated in Fig. 3 herein.

Thus, the hydroxyapatite complex of the present invention enables maintaining bioactivity of the hydroxyapatite sintered compact without losing it.

On the other hand, in JP 511, the calcium phosphate particle is modified with a silane coupling agent such as KBE9O3, and then reacted with the polymer-based material.

When the calcium phosphate particle is modified with a silane coupling agent such as KBE9O3, the silane coupling agent is bound to the calcium phosphate particle so as to coat the whole particle.

On this account, in the calcium phosphate-polymer complex of JP 511, the whole calcium phosphate particle is coated with a silane coupling agent, as illustrated in Fig. 4 herein. Therefore, in the calcium phosphate-polymer complex of JP 511, bioactivity of the calcium phosphate particle is lost

Fig. 3

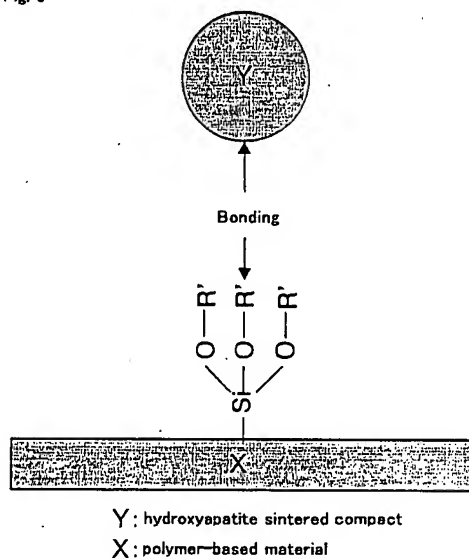
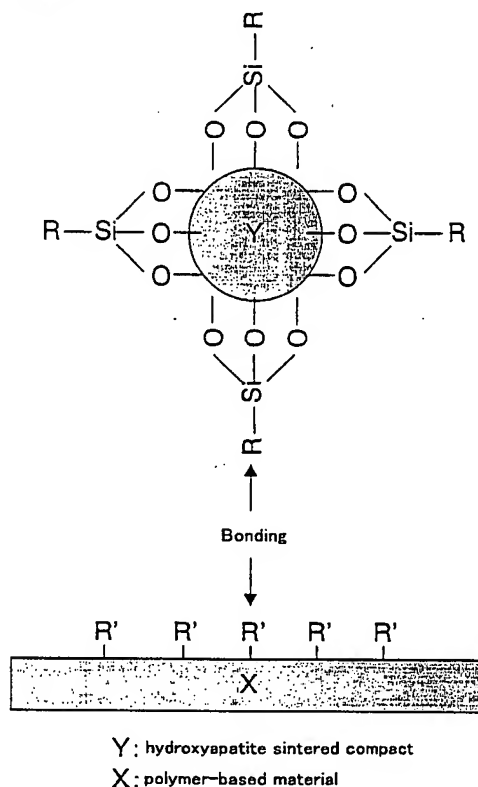


Fig. 4



Thus, the hydroxyapatite complex of the present invention is totally different in structure from the calcium phosphate-polymer complex disclosed in JP 511. That is, the hydroxyapatite complex recited in claims 19 and 20 has a unique structure that is not disclosed and suggested in JP 511. Therefore, both claims 19 and 20 should be allowable over JP 511.

The Sato reference was cited for its teaching that KBE903 is aminopropyl triethoxysilane. Other than this teaching, Sato fails to add anything of significance to the teachings of JP 511 with respect to the novel recitations in claims 9, 11, 13-17, 19 and 20.

Claims 9,11,19, and 20

The present invention aims at using the hydroxyapatite sintered compact without being subjected to pretreatment, and uses a hydroxyl group attached on the surface of the hydroxyapatite sintered compact for chemical bonding to the polymer-based material. In other words, in the present invention, the hydroxyapatite sintered compact is not modified, but the polymer-based material is modified.

On the contrary, *Hino* (US 5814681) discloses that an organic group is introduced on the surface of a hydroxyapatite powder by using an organic silane coupling agent, such as γ -methacryloxypropyl trimethoxysilane. Therefore, in the restorative composition for hard tissue of *Hino*, the whole hydroxyapatite powder is coated with an organic silane coupling agent (see Fig. 4 herein), as in the case of the calcium phosphate-polymer complex of JP 511.

As described herein, the hydroxyapatite complex recited in claims 9, 11, 19, and 20 has a unique structure that is not disclosed and suggested in *Hino*. Therefore, claims 9, 11,19, and 20 should be allowable over *Hino*.

Claims 13 through 17

Claims 13 through 17 are claims that depend directly or ultimately from claim 20. As herein described, the hydroxyapatite complex recited in claim 20 is a novel hydroxyapatite complex. Therefore, the novel recitations of claims 13 through 17 that are directed to a medical material made of such a hydroxyapatite complex clearly could not be achieved on the basis of the teachings of JP 511 and *Hino*. Thus, it is apparent that the novel recitations of claims 13 through 17 are not rendered obvious by the teachings of the cited references.

Even though the teachings of the JP 511 and *Hino* references are deficient with respect to the novel recitations in Applicants' claims, the Examiner states that these claims are product-by-process claims and that the determination of patentability must be based on the product itself and not on its method of production. For the reasons set forth hereinafter, it is requested that the Examiner reconsider this position.

First, it is submitted that the recitation of "chemically bonded" in claims 9, 11, 13-17, 19 and 20 is a structural limitation which does not make these claims product-by-process claims. Accordingly, these claims clearly are distinguished by structural limitations over the teachings of the cited references.

Even if claims 9, 11, 19, 20 and dependent claims 13-17 are interpreted as product-by-process claims, it is submitted that the terminology "chemically bonded" implies a structure that should be considered when assessing the allowability of the claims over the prior art. The Examiner's attention is directed to Section 2113 of the Manual of Patent Examining Procedure wherein it is stated that the structure implied by process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the

product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

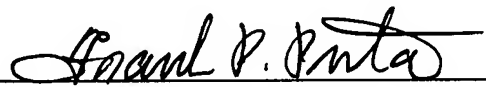
The Examiner's attention is also directed to the In re Garnero case set forth in Section 2113 wherein the CCPA held that the terminology "interbonded by interfusion" limited the structure of a claimed composite. In that case, the court also noted that terms such as "welded", "intermixed" and "ground in place", "press fitted", and "etched" are capable of construction as structural limitations. Accordingly, the language "chemically bonded" in the present claims should also be interpreted as a structural limitation which clearly defines the claims over the prior art.

The allowance of claims 1-8 and 18 is acknowledged.

In view of the above remarks, it is submitted that claims 9, 11, 13-17, 19 and 20 are allowable to Applicants, and formal allowance thereof is earnestly solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 
Frank P. Presta
Reg. No. 19,828

FPP:lcb
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100